

**OXYGEN - oxygen gas**  
**Capweld Inc**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

**OXYGEN COMPRESSED LABEL**

OXYGEN COMPRESSED USP UN 1072

PRODUCED BY AIR LIQUEFACTION

**WARNING: HIGH PRESSURE OXIDIZING GAS VIGOROUSLY ACCELERATES COMBUSTION. KEEP OIL AND GREASE AWAY. OPEN VALVE SLOWLY. STORE AND USE WITH ADEQUATE VENTILATION. USE ONLY WITH EQUIPMENT CLEANED FOR OXYGEN SERVICE AND RATED FOR CYLINDER PRESSURE. USE ONLY WITH PRESSURE REDUCING EQUIPMENT AND APPARATUS DESIGNED FOR OXYGEN SERVICE. USE A BACK FLOW PREVENTATIVE IN THE PIPING. CLOSE VALVE AFTER EACH USE AND WHEN EMPTY. CYLINDER TEMPERATURES SHOULD NOT EXCEED 52 C (125 F) USE IN ACCORDANCE WITH MATERIAL SAFETY DATA SHEET (MSDS)**



**GENERAL WARNINGS AND PRECAUTIONS**

Warning: for emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications Rx Only. Uninterrupted use of high concentrations of oxygen over a long duration without monitoring oxygen content of arterial blood may be harmful. Uninterrupted use of high concentrations of oxygen for more than 5 hours may be harmful. Do not attempt to use on patients who have stopped breathing, unless used in conjunction with resuscitative equipment.

**DO NOT REMOVE THIS PRODUCT LABEL**

**OXYGEN REFRIGERATED LIQUID LABEL**

OXYGEN REFRIGERATED LIQUID U.S.P. UN 1073

ALWAYS KEEP CONTAINER IN UPRIGHT POSITION

**WARNING: EXTREMELY COLD OXIDIZING LIQUID AND GAS UNDER PRESSURE. VIGOROUSLY ACCELERATES COMBUSTION. COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON IGNITION OR IMPACT. CAN CAUSE SEVERE FROSTBITE.**

STORE AND USE WITH ADEQUATE VENTILATION. KEEP OIL, GREASE, AND COMBUSTIBLES AWAY. NO SMOKING IN CONTAINER AREA. DO NOT USE OR STORE NEAR HEAT OR OPEN FLAME. USE ONLY WITH EQUIPMENT CLEANED FOR OXYGEN SERVICE. DO NOT GET LIQUID IN EYES ON SKIN OR CLOTHING. FOR LIQUID WITHDRAWAL, WEAR FACE SHIELD AND GLOVES. DO NOT DROP USE HAND TRUCK FOR CONTAINER MOVEMENT. AVOID SPILLS. DO NOT WALK ON OR ROLL EQUIPMENT OVER SPILLS. CLOSE VALVE AFTER EACH USE AND WHEN EMPTY. USE IN ACCORDANCE WITH MATERIAL SAFETY DATA SHEET (MSDS).

FIRST AID: IN CASE OF FROSTBITE OBTAIN MEDICAL TREATMENT IMMEDIATELY.

**OXYGEN, REFRIGERATED LIQUID**

**USP  
UN1073**



LOT #: \_\_\_\_\_  
CONTENTS: \_\_\_\_\_ LITERS

**↑ ALWAYS KEEP CONTAINER IN UPRIGHT POSITION. ↓**

**WARNING:** EXTREMELY COLD OXIDIZING LIQUID AND GAS UNDER PRESSURE.  
VIGOROUSLY ACCELERATES COMBUSTION.  
COMBUSTIBLES IN CONTACT WITH LIQUID OXYGEN MAY EXPLODE ON IGNITION OR IMPACT.  
CAN CAUSE SEVERE FROSTBITE.

Keep oil, grease, and combustibles away.  
Use only with equipment cleaned for oxygen service.  
Store and use with adequate ventilation.  
Do not get liquid in eyes, on skin or clothing.  
For liquid withdrawal, wear face shield and gloves.  
Do not drop. Use hand truck for container movement.  
Avoid spills. Do not walk on or roll equipment over spills.  
Close valve after each use and when empty.  
Use in accordance with the Material Safety Data Sheet (MSDS).

**FIRST AID:** IN CASE OF FROSTBITE, obtain medical treatment immediately.

**WARNING:** For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Rx only.

Uninterrupted use of high concentrations of oxygen over a long duration, without monitoring its effect on oxygen content of arterial blood, may be harmful. Use only with pressure reducing equipment and apparatus designed for oxygen. Do not attempt to use on patients who have stopped breathing, unless used in conjunction with resuscitative equipment.

Produced by Air Liquefaction  
**DO NOT REMOVE THIS PRODUCT LABEL.**



**233 E. RANKIN STREET  
JACKSON, MS 39205**

48138  
REV. 02/03

## OXYGEN CERTIFICATE OF ANALYSIS

CUSTOMER \_\_\_\_\_ VENDOR / SUPPLIER \_\_\_\_\_ THIS  
LETTER IS TO PROVIDE YOU WITH THE  
CERTIFICATION YOU REQUESTED FOR OXYGEN USP LOT NUMBER  
\_\_\_\_\_ SUPPLIED TO YOU IN  
CYLINDERS / VESSELS BY OUR LOCATION

These cylinders were filled in accordance with the Standard Operating Procedures utilized for the manufacture of Medical Gases. By

following these procedures, our location ensures that products are safely manufactured in compliance with FDA's Current Good Manufacturing Practices (cGMP) Regulations.

CAUTION: VENDOR SUPPLIES THIS CERTIFICATION TO CUSTOMER TO ASSIST CUSTOMER IN ENSURING COMPLIANCE WITH 21 CFR 211.84. THIS

CERTIFICATION DOES NOT ELIMINATE CUSTOMERS OBLIGATION TO COMPLY WITH OTHER PORTIONS OF 21 CFR 210 AND 211, INCLUDING BUT NOT

LIMITED TO 21 CFR 211.165 (FINISHED PRODUCT TESTING) FOR CYLINDERS AND VESSELS FILLED FROM THESE SUPPLY CYLINDERS. THESE CYLINDERS ARE NOT CERTIFIED FOR INSTRUMENT CALIBRATION.

TEST REQUIREMENT	USP SPECIFICATION	LOT ANALYSIS
IDENTIFICATION	PASS	
ODOR	PASS	
CARBON DIOXIDE	LESS THAT 0.03%	
CARBON MONOXIDE	LESS THAT 0.001%	
ASSAY	GREATER THAN 99.0%	

\*

NOTE: The USP/NF exempts facilities that manufacture Oxygen USP by the Air Liquefaction process from the tests for Carbon Dioxide and Carbon Monoxide.

As our label states, the Oxygen USP being supplied is manufactured by the Air Liquefaction Process.

The methodology being used to perform the USP / NF Test for Assay is indicated below: Paramagnetic Analyzer Model # \_\_\_\_\_  
J 700 a1

REVISION 1.0  
CERTIFICATE OF ANALYSIS - OXYGEN USP



Number	Title	Revision Number
J 700 a1	Certificate of Analysis - Oxygen USP	1.0

Customer

Vendor / Supplier

_____	_____
_____	_____
_____	_____

This letter is to provide you with the Certification you requested for Oxygen, USP, Lot # \_\_\_\_\_  
 Supplied to you in cylinders / vessels by our location.

These cylinders were filled in accordance with the Standard Operating Procedures utilized for the manufacture of Medical Gases. By following these procedures, our location ensures that products are safely manufactured in compliance with FDA's Current Good Manufacturing Practices (cGMP) Regulations.

**CAUTION:** Vendor supplies this certification to customer to assist customer in ensuring compliance with 21 CFR 211.84. This certification does not eliminate customer's obligation to comply with other portions of 21 CFR 210 & 211 including but not limited to 21 CFR 211.165 (finished product testing) for cylinders and vessels filled from these supply cylinders. These cylinders are not certified for instrument calibration purposes.

Test / Requirement	USP Specification	Lot Analysis
Identification	Pass	
Odor	Pass	
Carbon Dioxide	< 0.03 %	*
Carbon Monoxide	< 0.001 %	*
Assay	> 99.0 %	

\* **NOTE:** The USP/NF exempts facilities that manufacture Oxygen USP by the Air Liquefaction process from the tests for Carbon Dioxide and Carbon Monoxide. As our label states, the Oxygen USP being supplied is manufactured by the Air Liquefaction Process.

The methodology being used to perform the USP / NF Test for Assay is indicated below:

Paramagnetic Analyzer                      Model # \_\_\_\_\_

Supplier Signature \_\_\_\_\_ Date \_\_\_\_\_

<b>OXYGEN</b>			
oxygen gas			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:52849-100

<b>Route of Administration</b>	RESPIRATORY (INHALATION)
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Oxygen (UNII: S88TT14065) (Oxygen - UNII:S88TT14065)	Oxygen	99 L in 100 L

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52849-100-01	396 L in 1 CYLINDER		
2	NDC:52849-100-02	663 L in 1 CYLINDER		
3	NDC:52849-100-03	2266 L in 1 CYLINDER		
4	NDC:52849-100-04	3455 L in 1 CYLINDER		
5	NDC:52849-100-05	6910 L in 1 CYLINDER		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved medical gas		01/01/1952	

**Labeler** - Capweld Inc (033340977)

**Registrant** - Capweld Inc (033340977)

### Establishment

Name	Address	ID/FEI	Business Operations
Capweld Inc		033340977	manufacture

Revised: 1/2010

Capweld Inc